ROLE OF YOGA AS AN ADJUVANT THERAPY IN THE MANAGEMENT OF METABOLIC SYNDROME: A RANDOMIZED CONTROL TRIAL

A synopsis of the thesis for the award of Degree of

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In

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TABLE OF CONTENTS

S.No.	Topic	Page No.
1.	Introduction	3
2.	Aim and objectives	5
4.	Brief review of literature	6
5.	Methodology	7
6.	Results	14
7.	Discussion	23
8.	Conclusion	24
9.	References	26
10.	Appendix	29

1. Introduction

1.1 Background

Metabolic Syndrome

Metabolic syndrome (MetS) is a cluster of conditions that occur together, increasing an individual's risk of heart disease, stroke, and type 2 diabetes. These conditions include increased blood pressure, high blood sugar, excess body fat around the waist, and abnormal cholesterol or triglyceride levels. While each of these conditions is a risk factor on its own, having them collectively significantly boosts the chances of developing serious health issues compared to having just one condition.[1]

Historical evolution of the concept.

The concept of metabolic syndrome has evolved over time. It was first recognized in the 20th century, with various names and criteria proposed to describe the cluster of metabolic abnormalities associated with an increased risk of cardiovascular diseases and diabetes. The term "metabolic syndrome" itself gained prominence in the late 1980s and early 1990s as researchers and clinicians began to understand the interconnectedness of metabolic risk factors.[2]

1.2 Diagnostic Criteria for Metabolic Syndrome

Overview of diagnostic criteria developed by WHO, IDF, NCEP-ATP III, with specifics on each.

The criteria for diagnosing metabolic syndrome has been developed by several organizations, each with slight variations in their definitions. The most commonly referenced are from the World Health Organization (WHO), the International Diabetes Federation (IDF), and the National Cholesterol Education Program‟s Adult Treatment Panel III (NCEP-ATP III). These criteria focus on a combination of risk factors, including abdominal obesity, elevated fasting plasma glucose, high blood pressure, high triglycerides, and low HDL (high-density lipoprotein) cholesterol levels. The presence of a certain number of these factors leads to a diagnosis of metabolic syndrome, indicating an increased risk of cardiovascular diseases and type 2 diabetes.

The **WHO Criteria (1998)** requires the presence of diabetes mellitus, impaired glucose tolerance, impaired fasting glucose, or insulin resistance, and two or more of the following conditions:[3]

- Elevated blood pressure: systolic ≥140 mm Hg or diastolic ≥90 mm Hg or treatment of previously diagnosed hypertension.
- Dyslipidemia: triglycerides ≥150 mg/dL or HDL cholesterol <35 mg/dL in males and <39 mg/dL in females.
- Central obesity: waist-to-hip ratio >0.90 for males, >0.85 for females, or BMI >30 kg/m2.
- Microalbuminuria: urinary albumin excretion rate ≥20 µg/min or albumin to creatinine ratio ≥30 mg/g.

The **NCEP-ATP III Criteria (2001)** requires the presence of three or more of the following conditions:[4]

- Abdominal obesity: waist circumference >102 cm in males and >88 cm in females.
- Triglycerides ≥150 mg/dL.
- HDL cholesterol <40 mg/dL in males and <50 mg/dL in females.
- Blood pressure ≥130/85 mmHg or the use of medication for hypertension.
- Fasting glucose ≥100 mg/dL or the use of medication for hyperglycemia.

The **IDF Criteria (2005)** places more emphasis on central obesity as a mandatory criterion, defined differently for different ethnic groups, with additional factors including: [5]

- Central obesity: waist circumference ≥90 cm for South Asian men and ≥80 cm for South Asian women, with ethnicity-specific values for other groups.

Plus, any two of the following four factors:

- Triglycerides ≥150 mg/dL or specific treatment for this lipid abnormality.
- HDL cholesterol <40 mg/dL in males and <50 mg/dL in females or specific treatment for this lipid abnormality.
- Blood pressure ≥130/85 mmHg or treatment of previously diagnosed hypertension.
- Fasting plasma glucose ≥100 mg/dL or previously diagnosed type 2 diabetes.

1.3 The potential of Yoga in addressing physical and mental aspects of MetS

Conventional treatment for metabolic syndrome focuses on lifestyle changes and pharmacotherapy, but often overlooks the holistic impact of the syndrome, including psychological well-being and life quality. Herein lies the rationale for integrating yoga into the treatment regimen. Yoga, with its blend of physical postures (asanas), controlled breathing (pranayama), and meditation (dhyana), may offer a multifaceted solution, potentially improving both physical and mental health aspects.[6]

Benefits of Yoga in MetS

Yoga offers a comprehensive spectrum of health benefits, integrating physical, mental, and emotional wellness, as an adjuvant therapy for metabolic syndrome, (Balaji et al., 2023).[7] It is recognized as a holistic healthcare intervention that addresses both physical symptoms and psychological factors associated with metabolic syndrome (Kalra, 2021).[8] Studies have shown that regular yoga practice significantly improves lipid profiles, a crucial aspect in the management of metabolic syndrome (Ghazvineh et al., 2022).[9] Additionally, specific yoga modules have been designed and validated for treating obesity and related metabolic disorders, highlighting yoga's adaptability to patient-specific needs (Chobe et al., 2021).[10] Furthermore, yoga-based lifestyle intervention is considerably effective in managing metabolic syndrome, especially when compared to dietary changes alone (Yadav et al., 2019).[11] These insights collectively underscore the potential of yoga as a valuable adjunct therapy in the holistic management of metabolic syndrome.

2. Aim and Objectives

Aim: To investigate the efficacy of Yoga as an adjuvant therapy in MetS compared to standard medical management alone

Objectives: To investigate mean changes in anthropometric, cardiovascular, blood sugars and psychological measurements among individuals with Met S in Adjuvant Yoga Therapy (AYT) and Standard Medical Management (SMM) at enrolment, 3rd& 6th month of follow up.

3. Research Question

Does Yoga as an adjuvant therapy help in management of MetS?

4. Brief Review of Literature

Systematic review and meta-analysis conducted on effect of yoga on anthropometry, quality of life and lipid profile in patients with obesity and central obesity concluded that yoga can significantly improve anthropometric parameters by reducing total cholesterol and triglycerides levels. ***Kim et al***.[12] conducted a systemic review of controlled trials on yoga for adults with Type-II diabetes at West Virginia university school of public health, USA (2015). This study aimed to evaluate available evidence from prospective controlled trials regarding the effect of yoga based programs on specific health outcomes pertinent to Type-II diabetes mellitus management. 33 papers reporting findings from 25 controlled trials (13 randomized, 12 randomized) met the inclusion criteria (N=2170 participants). Study quality was evaluated using the PEDro scale. Data‟s were collected and analyzed. This study suggests that, yogic practices may promote significant improvements in several indices of importance in Type-II diabetes mellitus management, including glycemic control, lipid levels and body composition

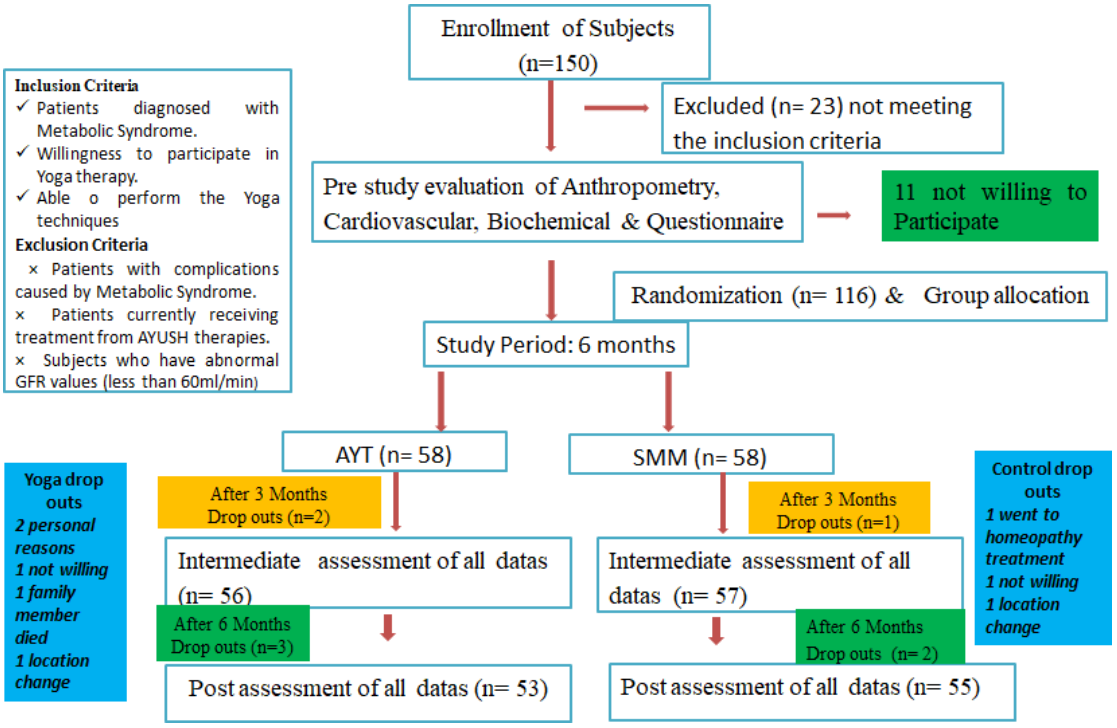
Chatruvedi, et.al, [13]concluded that yoga helps in improving the glycemic index, serum lipid profile, TSH in peri-menopausal women. Thus it can be effectively used to improve the quality of life in peri-menopausal women. ***Astorino T, et al***[14]said that Pranayama and yoga asanas can be helpful in patients with lipid metabolism disorders such as coronary artery disease, diabetes mellitus and dyslipidemia. ***Deepali k, et.al***[15]concluded that, 12 week yoga based lifestyle intervention had a positive impact on oxidative stress in adults with metabolic syndrome**.** ***Ranjani*** *H, et.al,* [16]concludes that, implementation of a 17 week standardized yoga program at the school level significantly decreased stress, improved attention and concentration, metabolic and clinical parameters in Indian adolescents. ***Shashikiran HC, et.al****,* [17]yoga-based lifestyle could be explored as a non-invasive and cost-effective measure in the mitigation of atherosclerotic cardiovascular disease risk in predisposed individuals. ***Stephanie J, et.al,***[18] yoga combined with health education may lead to improvements in quality of life outcomes among adults at risk for metabolic syndrome over conventional standardized group health education. ***Sabri A, et.al****,* [19]

Summary of review of literature

Yoga Therapy has been shown effective in management of MetS as well as its risk factors. However to the best of our knowledge a comprehensive study of all dimensions has not been done. Intermediate impact and long term impact have not been studied together. In this study we have tried to fill the lacunae.

5. Methodology

5.1.1 Consort chart


Inclusion Criteria
✓ Patients diagnosed with Metabolic Syndrome.
✓ Willingness to participate in Yoga therapy.
✓ Able o perform the Yoga techniques
Exclusion Criteria
× Patients with complications caused by Metabolic Syndrome.
× Patients currently receiving treatment from AYUSH therapies.
× Subjects who have abnormal GFR values (less than 60ml/min)
Enrollment of Subjects (n=150)
Excluded (n= 23) not meeting the inclusion criteria
Pre study evaluation of Anthropometry, Cardiovascular, Biochemical & Questionnaire
11 not willing to Participate
Randomization (n= 116) & Group allocation
Study Period: 6 months
AYT (n= 58)
SMM (n= 58)
Yoga drop outs
2 personal reasons
1 not willing
1 family member died
1 location change
After 3 Months Drop outs (n=2)
After 3 Months Drop outs (n=1)
Control drop outs
1 went to homeopathy treatment
1 not willing
1 location change
Intermediate assessment of all datas (n= 56)
Intermediate assessment of all datas (n= 57)
After 6 Months Drop outs (n=3)
After 6 Months Drop outs (n= 2)
Post assessment of all datas (n= 53)
Post assessment of all datas (n= 55)

5.2 Study Design

This study is an open labelled single centric randomised controlled trial. Prior permission was obtained from the Institutional Human Ethics Committee (IHEC) for the study **[Project No: PhD. AVMC/IEC2019/015]** and Registered with the Clinical Trials Registry of India, **Reg. No: CTRI/2018/08/ 015514.**

5.3 Place of Study

It was conducted at a tertiary care hospital as per the Standard Operating Procedure (SOP) which in line with IDF & AHA. The patients screened for eligibility by the clinicians at the Dept. of General Medicine (GM) out-patient services, AVMCH. Patients who were eligible were referred to Centre for Yogic Sciences (CYS), AVMCH, Puducherry, India

5.4 Patient selection

5.4.1Study Population

All patients newly diagnosed with MetS

5.4.2 Inclusion Criteria

1. Patients diagnosed with Metabolic Syndrome.
2. Willingness to participate in Yoga therapy.
3. Capability to perform the Yoga protocol techniques.

5.4.3 Exclusion Criteria

1. Patients with complications caused by Metabolic Syndrome.
2. Patients currently receiving treatment from AYUSH therapies.
3. Subjects who have abnormal GFR values (less than 60ml/min)

5.4.4 Study Subjects

Our study involves patients newly diagnosed with metabolic syndrome fulfilling inclusion criteria.

5.4.5 Sample Size

Sample size is 48 for each group arrived by using sample size calculator. Therefore minimum required sample size would be 96. Adding a dropout rate at 20%, 116 sample size is required to fulfill the minimum required sample size.

$$n_{per/group} = \frac{\left(\sigma_1^2 + \sigma_2^2\right)\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{\Delta^2}$$

Zα/2is the Z-value for the chosen alpha level (for α = 0.05, it's approximately 1.96).

Zβis the Z-value for the chosen power (for β corresponding to a power of 0.80, it's approximately 0.84).

SD1and SD2are the standard deviations for Group 1 and Group 2, respectively.

Δ is the difference in means (in our case, 6.3).n_1 = 48

Considered 20% of attrition$n_1 = n_1 + n_1 \times 20\%$

= 48 + 48+ 20

= 58 in each group

Total Sample Size= 116

5.5 Patient Allocation/ Randomisation

Patients fulfilling inclusion criteria were randomly assigned to Adjuvant Yoga Therapy (AYT) & Standard Medical Management (SMM) on 1:1 ratio using computer generated random numbers. Allocated concealment was ensured using open envelope. .All those who consented to participate in the study were randomly allocated into Adjuvant Yoga Therapy (AYT) & Standard Medical Management (SMM) groups on 1:1 ratio. SMM interviewed at initial, 3rd& 6th Month. AYT in additional to SMM were interviewed initially, 3rd (36 supervised Yoga therapy sessions) & 6th month (72 supervised Yoga therapy sessions).

5.6 Outcome Measures/ Tools Used

S. No	Parameters	Variables
1	Anthropometry	BMI, waist & hip circumference, Neck circumference, waist hip circumference ratio
2	Cardiovascular	Pulse Rate, systolic and diastolic blood pressure
3	Bio- chemical	Fasting and Postprandial Blood sugar, HbA_1c, Fasting Lipid profile
4	Psychological assessment	Ferrans & Power Quality of Life Index generic version III (QOL) and Perceived Stress Scale (PSS)

5.6.1 Anthropometric Parameters

Height:

Height was measured using a Stadiometer [Easy care TM (NO:26 SM)] mounted on the wall. The precise height in centimeters was recorded.

Weight:

Weight was calculated using an automated weighing instrument (Charder Electronics, Taichung, Taiwan 2013), which has a maximum weight restriction of 300 kg and a minimum weight limit of 2 kg.

BMI was calculated using

$$BMI = \frac{\text{Weight in Kilograms}}{\text{Height in Metres}^2}$$

Waist, Hip & Neck Circumference

Using a flexible narrow non- stretch tape in adults wearing minimal clothing

Waist- Measure waist at narrowest point

Hip- Measure hips at widest point

$$WHR = \frac{\text{Waist Circumference}}{\text{Hip Circumference}}$$

Wrap the measuring tape around the neck, beginning at about one inch from the meeting of your neck and shoulders. This may also coincide with the bottom part

of the Adam's apple. Hold the tape tight. Come fully around the neck, leaving no dangling space in between the neck and the tape. It was recorded in centimeters (CMs)

5.6.2 Cardiovascular Parameters

An automated OMRON BP apparatus with the model number TMB -1490-A was used to measure. Pulse Rate (PR), Systolic Blood Pressure (SBP), and Diastolic Blood Pressure (DBP) were recorded from the apparatus.

- PR/ min
- BP in mmHg

5.6.3 Biochemical Parameters

Sample Collection and Storage:

Biochemistry: After informed consent, 8 ml of blood was drawn for serum preparation, and an additional 2 ml was collected in EDTA vacationers for plasma preparation. All biochemical parameters were estimated using IFCC-approved methods, with internal quality control (QC) based on Bio-Rad QC and external quality assessment through the EQAS scheme by CMC, Vellore. All the investigations done at AVMCH central laboratory.

5.6.4 Psychological assessment

- Perceived Stress Scale (PSS)
- The Ferrans and Powers Quality of Life Index (QLI) Generic version III

5.7 Yoga Therapy Protocol

Based on traditional references and previous research studies the following practices were shortlisted after expert validation (Table 1).

Table 1: Yoga Therapy Protocol

S.No.	Yogic Techniques	Rounds	Duration (min)
1.	SookshamVyayama- Mainly for the abdomen, chest and hip	3 times each	5
2.	Aruna suryanamaskar variation I– 3 rounds	3 times	5
3.	Ardhakati & Katichakrasana	3 times	5
4.	Trikonasana	3 times	2
5.	Vakrasana	3 times	2
6.	Bharatwaja asana	3 times	2
7.	Paschimottanasana	3 times	2
8.	Nava asana	3 times	2
9.	Pavanamukta Series (As eka & dwi padakriya and asana)	3 times	5
10.	Jatara Paravrithi	3 times	2
11.	Sarvanga asana & Viparitakarani	3 times	10
12.	Chandra Nadi Pranayama	9 rounds	3
13.	Nadi Shuddhi Pranayama	9 rounds	5
14.	Brahma Mudra	9 rounds	8
15.	Kavi (Sadanta) Pranayama	9 rounds	3
16.	Kaya kriya: dynamic body relaxation with movements of lower, upper limbs and head and neck with breathing	Each set 3 rounds	10
17.	Spandha Nishpandha Kriya: self-directed complete tensing of whole body followed by its instant relaxation	3 times	3
18.	Shavasana with Savithri pranayama Breathing In for 4 secs, hold in 2 secs, breathing out for 2 secs, hold out for 2 secs	3 rounds	3
19.	Shavasana with Pranava pranayama: Breathing in and then breathing out with the sounds of aaa... uuu… and mmm…	Each set 3 rounds	10
20.	Shavasana with deep inhalation & exhalation	1 round	5

5.8 Procedure

i. Patients who were eligible were referred to Centre for Yogic Sciences (CYS), by GM of AVMCH.

ii. Once the patient came to CYS, detailed counselling was done regarding need for the study & nature of the study as RCT.

iii. They were explained about the possibilities of 50% chances of getting either side of AYT & SMM groups.

iv. All those who consented to participate in the study were randomly allocated into AYT & SMM on 1:1 ratio was done

- SMM group of 58 subjects who received only the medical management interviewed at initial, 3^{rd}& 6^{th} Month.
- AYT in additional to SMM, they were interviewed initially, 3^{rd} (36 supervised Yoga therapy sessions) & 6^{th} month (72 supervised Yoga therapy sessions)

v. All data recorded at enrolment, 3^{rd}& 6^{th} month were considered for analysis.

vi. If patients reported increase of symptoms related to DM or its complications, appropriate medical management was initiated.

vii. In case of patients who had similar glycaemic status as that of enrolment value, and who remained asymptomatic, they were advised to intensive life style modifications.

5.9 Statistical Analysis

- Statistical analysis was carried out using JASP 0.17.2.1 (2023 version)
- Fisher‟s exact test was used for comparing gender distribution in the two groups.
- Repeated Measures of ANOVA (RM ANOVA) used to calculate Time effects at enrolment, at 3^{rd}& 6^{th} month & Group effects between the groups and within the groups
- P value <0.05 was considered as significant.

6. Results

Patients related to diabetes & hypertensions were asymptomatic and did not show any complications during the interview at 3 months & 6 months point of data collection **both in AYT & SMM**

Table: 2 Comparison of Age & Gender between AYT & SMM groups

		Group			Chi-Square Test	p-value
		Study	Control	Total		
Age Group	20-30	3 (5.5%)	3 (5.5%)	6 (5.5%)	1.440	0.696
	30-40	14 (26.4%)	11 (20%)	26 (23.6%)		
	40-50	24 (45.3%)	31 (56.4%)	56 (50.9%)		
	50-60	12 (21.8%)	10 (18.2%)	22 (20%)		
Gender	Female	21 (39.6%)	23 (41.8%)	44 (40%)	0.054	0.816
	Male	32 (60.4%)	32 (58.2%)	66 60%)		

Table: 3 Comparison of Cardiovascular, Anthropometric, Glycemic, Lipid, PSS and QoL in Pretest between AYT & SMM groups

Parameters		AYT		SMM		Independent t test	P value
		Mean	Std	Mean	Std		
BMI	Pre	31.582	4.804	31.389	3.134	0.247	0.805
WC	Pre	96.953	5.498	98.018	4.341	-1.12	0.265
HC	Pre	100.038	7.19	100.3	5.87	-0.208	0.836
R	Pre	0.931	0.073	0.981	0.074	-0.351	0.727
NC	Pre	33.934	1.912	35.418	2.872	-3.149	0.002
FBS	Pre	187.83	18.733	193.364	17.678	-1.579	0.117
PPBS	Pre	239.717	34.943	248.909	21.327	-1.657	0.1

Parameters		AYT		SMM		Independent t test	P value
		Mean	Std	Mean	Std		
HbA_1c	Pre	9.587	1.91	9.034	0.546	2.062	0.042
TC	Pre	263.245	36.669	250.127	28.352	2.084	0.04
TG	Pre	289.849	55.163	268.491	65.837	1.824	0.071
HDL	Pre	33.792	11.611	33.6	7.358	0.103	0.918
LDL	Pre	180.943	23.063	177.655	15.317	0.876	0.383
PSS	Pre	29.887	2.614	30.182	2.01	-0.659	0.511
Qol1	Pre	12.549	0.686	12.558	0.902	-0.059	0.953
Qol2	Pre	12.478	1.124	12.193	1.087	1.338	0.184
Qol3	Pre	12.843	1.433	12.818	1.596	0.084	0.933
Qol4	Pre	12.515	1.289	12.676	1.382	-0.627	0.532
Qol	Pre	12.588	0.567	12.543	0.561	0.416	0.678

BMI- Body Mass Index

WC- waist Circumference

HC- Hip Circumference

Ratio- WC/ HC

NC- Neck Circumference

FBS- Fasting Blood Sugar

PPBS- Post Prandial Blood Sugar

HbA_1c- Glycosylated Hemoglobin

TC- Total Cholesterol

TG- Triglycerides

HDL- High Density Lipid

LDL- Low Density Lipid

PSS- Perceived Stress Scale

Qol- Quality of Life

Table: 4 Comparison of Cardiovascular, Anthropometric, Glycemic, Lipid, PSS & QoL between AYT & SMM before, Intermediate and after 6 months.

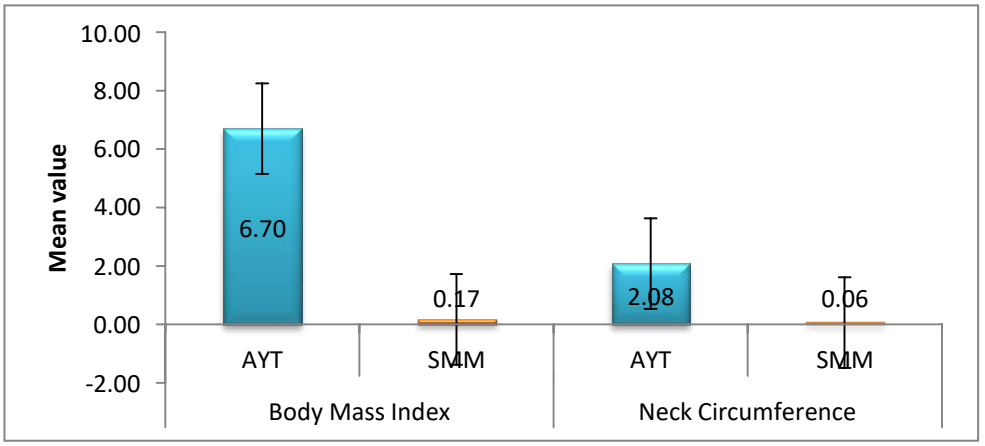
		Study		Control		Independent t-test	p-value
Parameters	Period	Mean	Std. Deviation	Mean	Std. Deviation		
Pulse rate	Pre	82.755	9.557	83.636	7.912	-0.523	0.602
	Inter	77.358 a, c	6.218	80.764 a	7.775	-2.508	0.014
	Post	77.132 a, c	6.102	82.018 a	7.531	-3.696	< .001
RM ANOVA		25.45		12.998			
p- value		< .001		< .001			
Systolic Blood Pressure	Pre	139.736	11.775	143.582	8.139	-1.981	0.050
	Inter	129.981 a, c	7.824	136.273 a	12.099	-3.196	0.002
	Post	127.925 a, c	6.388	140.545	12.884	-6.412	< .001
RM ANOVA		104.031		7.7			
p- value		< .001		< .001			
Diastolic blood pressure	Pre	87.925	7.041	85.327	7.165	1.899	0.06
	Inter	81 a, c	5.189	83.891 a	5.213	-2.888	0.005
	Post	78.453 a, b, c	4.397	83.2 a	5.883	-4.736	< .001
RM ANOVA		116.983		6.864			
p- value		< .001		0.002			
Body Mass Index	Pre	31.582	4.804	31.389	3.134	0.247	0.805
	Inter	26.918 a,c	3.706	31.174	3.224	-6.375	< .001
	Post	24.881 a, b, c	2.776	31.217	3.009	-11.362	< .001
RMANOVA		78.877		0.156			
p- value		< .001		0.856			
Waist-circumference	Pre	96.953	5.498	98.018	4.341	-1.12	0.265
	Inter	95.792 a, c	5.429	98.336	3.683	-2.859	0.005
	Post	92.726 a, b, c	5.493	97.353	3.2	-5.372	< .001
RM ANOVA		88.228		1.462			
p- value		< .001		0.236			
Hip-circumference	Pre	100.038	7.19	100.3	5.87	-0.208	0.836
	Inter	100.396	6.362	100.036	5.542	0.314	0.754
	Post	99.396	6.362	99.7	5.35	-0.269	0.789
RM ANOVA		2.105		0.18			
p- value		0.127		0.835			
Ratio	Pre	0.931	0.073	0.981	0.074	-0.351	0.727
	Inter	0.801 a, c	0.073	0.986	0.064	-13.985	< .001
	Post	0.721 a, b, c	0.073	0.979	0.059	-20.146	< .001
RM ANOVA		0.098		0.169			

p- value	0.999			0.845			
Neck-circumference	Pre	33.934	1.912	35.418	2.872	-3.149	0.002
	Inter	32.755	1.989	35.427	2.568	-6.03	< .001
	Post	31.855 a, b, c	1.989	35.355	2.492	-8.047	< .001
RM ANOVA	2399.119			0.014			
p- value	< .001			0.986			
Fasting Blood Sugar	Pre	187.83	18.733	193.364	17.678	-1.579	0.117
	Inter	153.189 a, c	16.77	177.491 a	11.102	-8.911	< .001
	Post	128.623 a, b, c	10.728	187.327 b	20.639	-18.443	< .001
RM ANOVA	537.539			14.321			
p- value	< .001			< .001			
Post Prandial Blood Sugar	Pre	239.717	34.943	248.909	21.327	-1.657	0.1
	Inter	198.83 a, c	23.898	223.4 a	14.791	-6.45	< .001
	Post	167.585 a, b, c	18.578	249.364 b	13.876	-25.982	< .001
RM ANOVA	396.282			45.418			
p- value	< .001			< .001			
HbA_1c	Pre	9.587	1.91	9.034	0.546	2.062	0.042
	Inter	7.781 a, c	0.642	8.457 a	0.459	-6.313	< .001
	Post	6.668 a,b, c	0.676	8.936 a, c	0.621	-18.167	< .001
RM ANOVA	81.673			20.408			
p- value	< .001			< .001			
Total cholesterol	Pre	263.245	36.669	250.127	28.352	2.084	0.04
	Inter	222.094 a	32.643	245.618 a	27.832	-4.035	< .001
	Post	170.943 a, b, c	19.543	247.109 a	10.266	-25.486	< .001
RM ANOVA	176.563			0.451			
p- value	< .001			0.638			
Triglycerides	Pre	289.849	55.163	268.491	65.837	1.824	0.071
	Inter	256.264 a	59.264	234.418 a	54.11	2.002	0.048
	Post	157.264 a, b, c	31.152	236.036 a	7.579	-18.205	< .001
RM ANOVA	229.016			9.84			
p- value	< .001			< .001			
High Density Lipid	Pre	33.792	11.611	33.6	7.358	0.103	0.918
	Inter	48.358 a, c	8.923	36.727	7.536	7.328	< .001
	Post	55.679 a, b, c	5.853	36.655 a	9.417	12.554	< .001
RM ANOVA	189.571			2.624			
p- value	< .001			0.077			
Low Density Lipid	Pre	180.943	23.063	177.655	15.317	0.876	0.383
	Inter	161.151 a	18.616	159.036 a	15.717	0.639	0.524

	Post	146.151 a, b, c	18.616	173.727 b	15.527	-8.372	< .001
RM ANOVA	137.588			57.004			
p- value	< .001			< .001			
Perceived Stress Scale	Pre	29.887	2.614	30.182	2.01	-0.659	0.511
	Inter	24 a, c	2.512	28.2	2.453	-8.793	< .001
	Post	19.774 a, b, c	1.671	27.091 a	3.466	-13.892	< .001
RM ANOVA	267.313			32.88			
p- value	< .001			< .001			
QoL 1	Pre	12.549	0.686	12.558	0.902	-0.059	0.953
	Inter	15.927 a, c	1.879	13.903	1.272	6.58	< .001
	Post	20.108 a, b, c	2.538	15.439 a	1.959	10.725	< .001
RM ANOVA	300.663			83.63			
p- value	< .001			< .001			
QoL 2	Pre	12.478	1.124	12.193	1.087	1.338	0.184
	Inter	15.123 a, c	2.723	13.875	1.997	2.723	0.008
	Post	19.339 a, b, c	3.531	16.474 a, b	3.095	4.488	< .001
RM ANOVA	115.181			72.327			
p- value	< .001			< .001			
QoL 3	Pre	12.843	1.433	12.818	1.596	0.084	0.933
	Inter	14.885	3.259	14.544	1.706	0.684	0.495
	Post	19.072 a, b, c	3.465	15.728 a	2.112	6.08	< .001
RM ANOVA	88.103			41.117			
p- value	< .001			< .001			
QoL 4	Pre	12.515	1.289	12.676	1.382	-0.627	0.532
	Inter	15.109 a, c	3.261	14.545	2.482	1.014	0.313
	Post	20.872 a, b, c	3.666	16.798 a	3.504	5.905	< .001
RM ANOVA	205.66			44.425			
p- value	< .001			< .001			
Overall QoL	Pre	12.588	0.567	12.543	0.561	0.416	0.678
	Inter	15.403 a, c	1.926	14.121	1.01	4.352	< .001
	Post	19.826 a, b, c	2.112	15.942 a	1.508	11.032	< .001
RM ANOVA	310.634			218.242			
p- value	< .001			< .001			

The symbols ‘a’, ‘b’, & ‘c’ denote different types of statistical significance. *‘a’* indicate statistical significance compared to the pre measurement within the same group *‘b’* signifies the statistical significance of the change from the intermediate to the post measurement within the same group *‘c’* shows statistical significance between AYT & SMM groups at the same time point.

Fig: 1 & 2 Comparative Delta Analysis of Anthropometric Parameters in Pre and Post Between AYT and SMM Groups



#p<0.05, ##p<0.01, ###p<0.001 by Student's unpaired T test for intergroup comparisons.

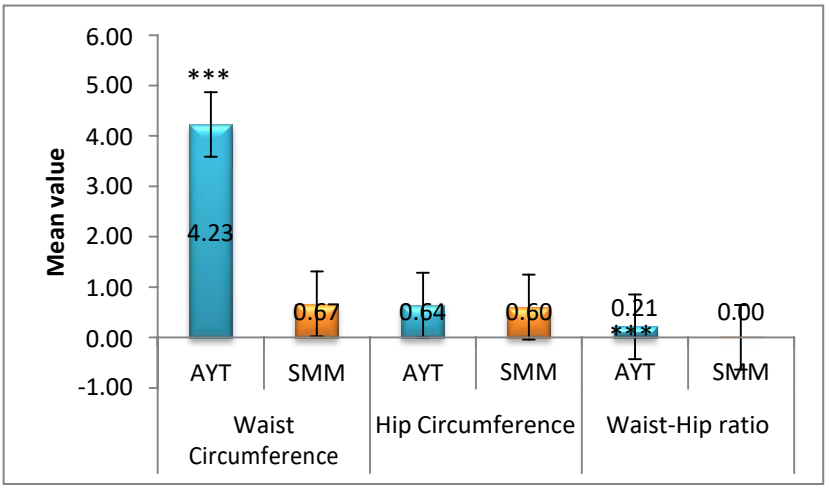


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Fig: 3 Comparative Delta Analysis of Cardiovascular Parameters in Pre and S Post between AYT& SMM

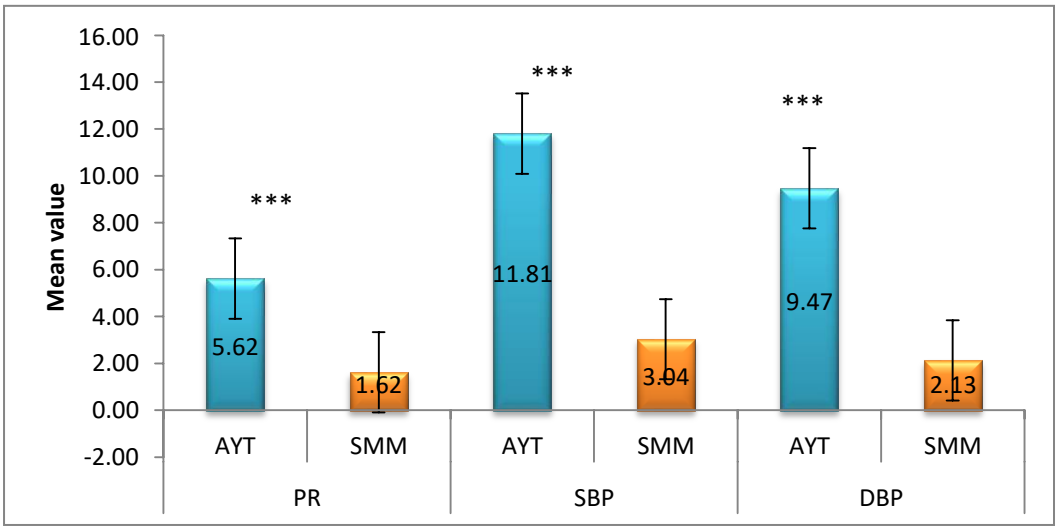

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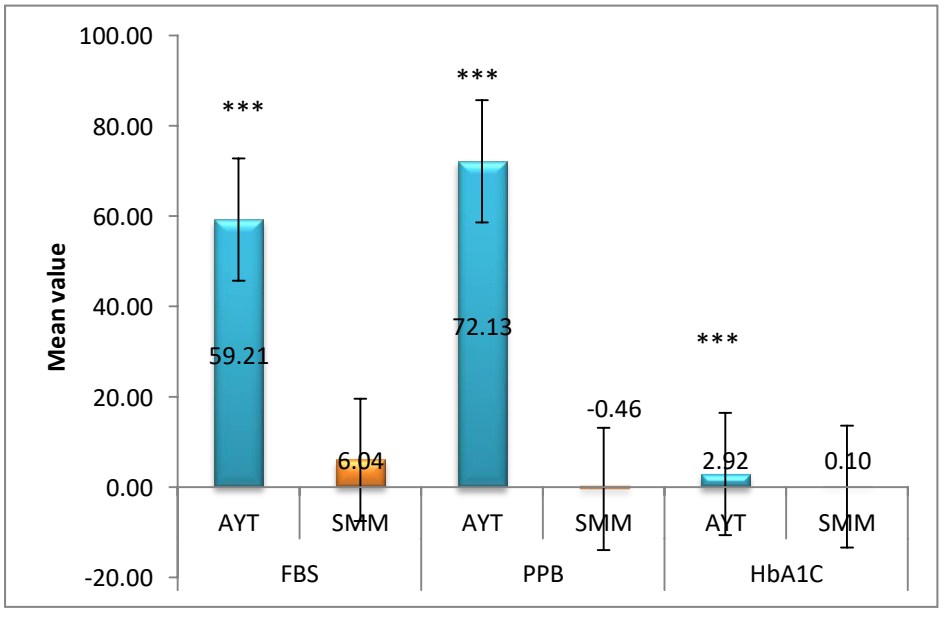
Fig: 4 Comparative Delta Analysis of Glycemic Parameters in Pre and Post Between AYT and SMM Groups



#p<0.05, ##p<0.01, ###p<0.001 by Student's unpaired T test for intergroup comparisons

Fig: 5 Comparative Delta analysis of Lipid parameters, in Pre and Post between AYT and SMM groups

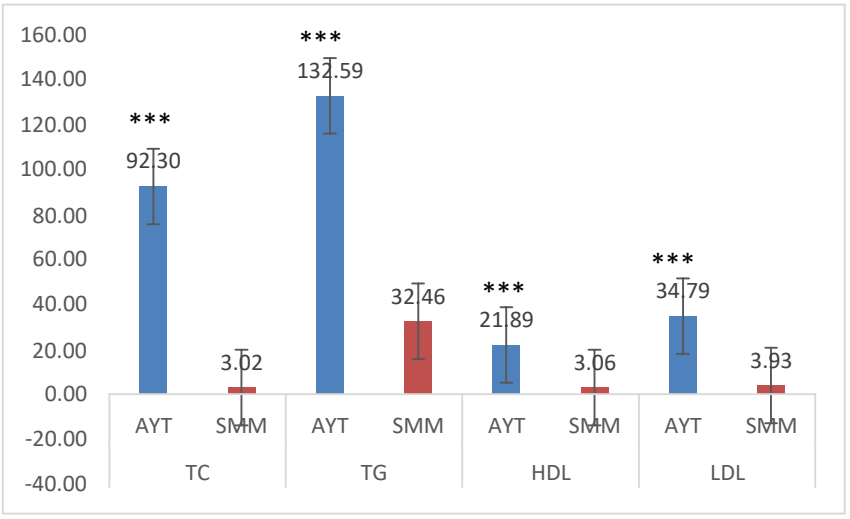


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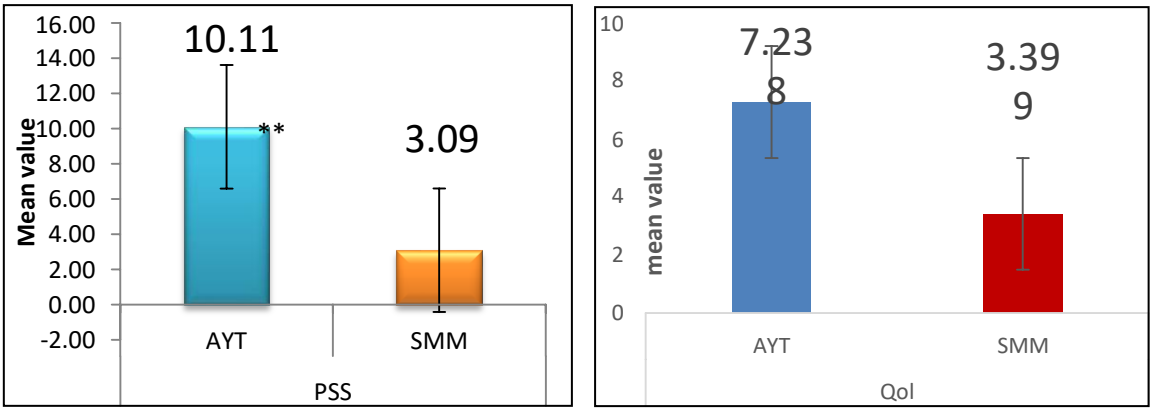
Fig: 6 & 7 Comparative Delta analysis of PSS overall QoL in Pre and Post between AYT and SMM



#p<0.05, ##p<0.01, ###p<0.001 by Student's unpaired T test for intergroup comparisons

Fig: 8 Forest plot on BMI

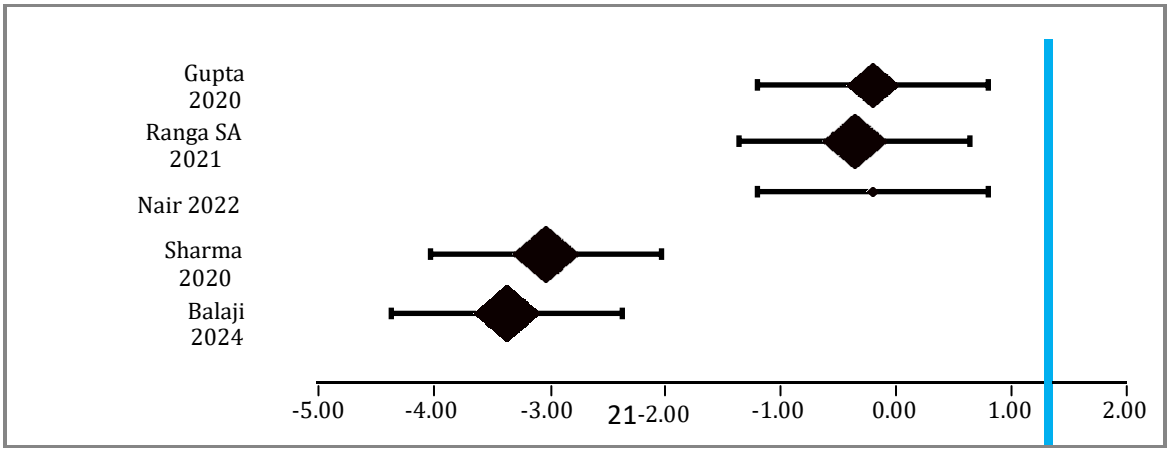


Fig: 9 Forest plot on HbA_1c

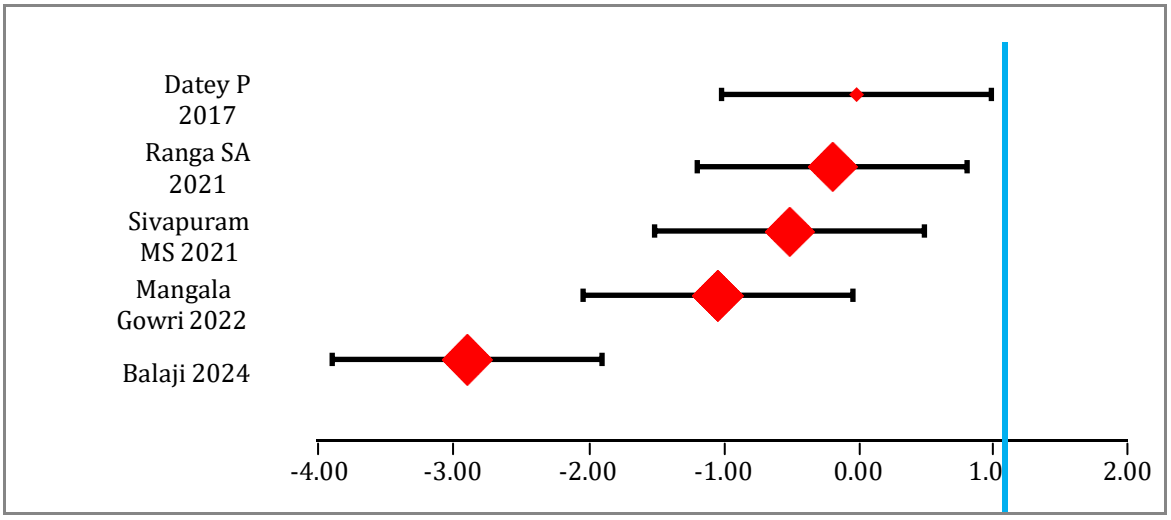
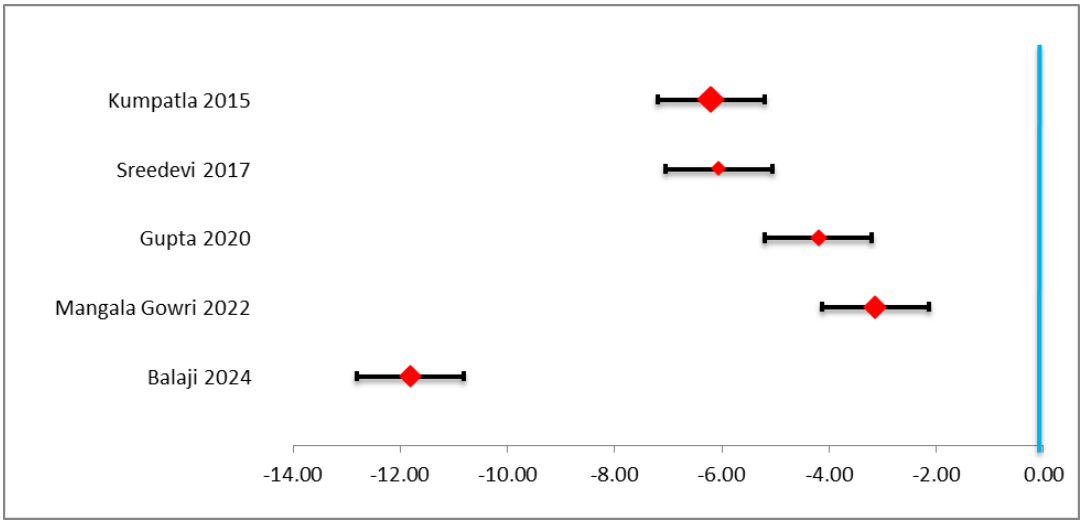
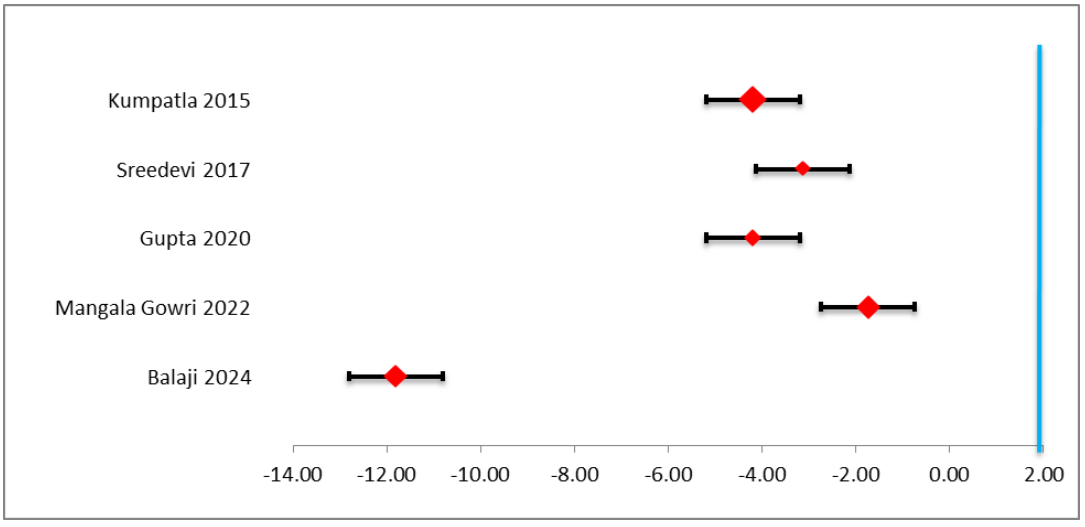


Fig: 10 & 11: Forest plot on SBP& DPB





7. Discussion

This study has investigated the efficacy of Yoga as an adjuvant therapy in MetS compared to standard medical management. The scope of the study encompasses demographic analysis such as age and gender, health outcomes such as blood pressure, blood sugar levels, lipid profiles, body weight, and stress levels, quality of life along with the **longitudinal follow-up** to observe the long-term effects and sustainability of yoga practice in MetS

Obesity Management through Yoga

In our recent investigation, we observed that participants engaging in regular yoga sessions demonstrated significant reductions in body mass index (BMI), waist circumference, and overall weight. These changes are indicative of yoga's potential to modulate body composition and reduce obesity-related health risks.[20, 21]

Hypertension management through Yoga

In our study, we observed a significant reduction in both systolic and diastolic blood pressure among participants following a sustained yoga practice. These findings are critical, considering hypertension's role as a primary risk factor for cardiovascular diseases. The reduction in blood pressure suggests that yoga may help in modulating the body's stress response and improving vascular function.[22, 23, 24]

Hyperglycaemia management through Yoga

Our research demonstrated significant reductions in both fasting blood sugar (FBS) and postprandial blood sugar (PPBS) levels, along with a notable decrease in HbA1C, indicating improved glycemic control. These results are pivotal as they suggest that regular yoga practice can substantially aid in regulating blood glucose levels, which is crucial for managing and preventing type II diabetes. [25, 26]

Hypertriglyceridemia and role of Yoga

In our research, we observed notable improvements in triglyceride levels among participants engaged in regular yoga practice over a sustained period. These findings align with the broader narrative of yoga's effectiveness in improving lipid metabolism and reducing cardiovascular risk factors. [27, 28]

HDL Levels and role of Yoga

In our study involving peri-menopausal women, we observed improvements in HDL levels alongside significant decreases in fasting blood sugar, HbA1c, total cholesterol, LDL, and the TC/HDL ratio. Although the changes in HDL were not statistically significant, they trended positively, suggesting potential benefits from prolonged or more intensive yoga practice.[29, 30]

We observed that participants engaging in regular Yoga Therapy sessions demonstrated significant reductions in Body Mass Index (BMI), Waist circumference, and overall weight. These changes are indicative of Yoga Therapy‟s potential to modulate body composition and reduce obesity-related health risks.Yoga's ability to improve mindfulness and body awareness also helps individuals make better food choices and recognize satiety cues.

8. Conclusion

This present study conclude that Yoga as an adjuvant therapy enhances the physical, physiological, bio chemical & psychological health.

Key Findings of the study are

i) Physiological and metabolic improvements:

- Adjuvant Yoga Therapy has demonstrated considerable effectiveness in reducing vital signs such as blood pressure and heart rate, which are crucial in the management of hypertension.
- Significant reductions were observed in fasting blood glucose and postprandial blood sugar levels among participants with hyperglycemia, indicating improved glycemic control.
- Participants with hypertriglyceridemia experienced notable decreases in triglyceride levels, showcasing yoga's potential in managing lipid metabolism.

ii) Impact on obesity:

- Substantial improvements in body mass index (BMI), waist circumference, and overall body weight were recorded, affirming yoga‟s effectiveness in addressing obesity and its associated health risks.

iii) Enhancement of mental well-being:

- A noteworthy reduction in stress levels and enhancements in various domains of quality of life were reported, highlighting the psychological benefits of regular yoga practice

This RCT is particularly relevant in the Indian context, given the high and growing prevalence of Metabolic Syndrome in the country. By exploring the impact of yoga, a practice deeply rooted in Indian culture, on Metabolic Syndrome, the study aims to provide valuable insights into holistic healthcare approaches, potentially enhancing patient outcomes and offering a complementary avenue to conventional medical treatment in a region significantly affected by this syndrome.

9. References

1. Metabolic syndrome: pathophysiology, management, and modulation by natural compounds - PMC [Internet].[Cited2024 Feb 4]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5933580
2. Kassi E, Pervanidou P, Kaltsas G, Chrousos G. Metabolic syndrome: definitions and controversies. BMC Med. 2011 May 5;9:48.
3. World Health Organization-Defined Metabolic Syndrome Is a Better Predictor of Coronary Calcium Than the Adult Treatment Panel III Criteria in American Men Aged 40–49 Years | Diabetes Care | American Diabetes Association [Internet]. [Cited 2024 Mar 6]. Available from: https://diabetesjournals.org/care/article/27/12/2977/26577/World-Health-Organization-Defined-Metabolic
4. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). JAMA. 2001 May 16;285(19):2486– 97
5. Prevalence of the Metabolic Syndrome Defined by the International Diabetes Federation Among Adults in the U.S. | Diabetes Care | American Diabetes Association [Internet]. [cited 2024 Mar 6]. Available from: https://diabetesjournals.org/care/article/28/11/2745/25200/Prevalence-of-the-Metabolic-Syndrome-Defined
6. Health Impacts of Yoga and Pranayama: A State-of-the-Art Review - PMC [Internet]. [cited 2024 Feb 4]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3415184
7. Balaji R, Bhavanani AB, Jatiya L, Ramanathan M. Yoga For Metabolic Syndrome: A Comprehensive Review: Life Sciences-Nursing. Int J Life SciPharma Res. 2023 Mar 1 ; L77–82.
8. Dutta D, Bhattacharya S, Sharma M, Khandelwal D, Surana V, Kalra S. Effect of yoga on glycemia and lipid parameters in type-2 diabetes: a meta-analysis. J Diabetes MetabDisord. 2021 Jun;20(1):349–67.
9. Ghazvineh D, Daneshvar M, Basirat V, Daneshzad E. The Effect of Yoga on the Lipid Profile: A Systematic Review and Meta-Analysis of Randomized Clinical Trials. Front Nutr [Internet]. 2022 [cited 2024 Feb 3];9. Available from:https://www.frontiersin.org/articles/10.3389/fnut.2022.942702

10. Chobe MP, Nanjundaiah RM, Chobe S. Designing and validation of a yoga-based module for obesity with metabolic comorbidities. J Complement Integr Med. 2020 Jul 12; 18(1):159–63.
11. Yadav R, Yadav RK, Khadgawat R, Pandey RM. Comparative efficacy of a 12 week yoga-based lifestyle intervention and dietary intervention on adipokines, inflammation, and oxidative stress in adults with metabolic syndrome: a randomized controlled trial. TranslBehav Med. 2019 Jul 16;9(4):594–604.
12. Innes KE, Selfe TK. Yoga for Adults with Type 2 Diabetes: A Systematic
13. Review of Controlled Trials. J Diabetes Res. 2016; 2016:6979370.
14. ChaturvediA et al. Efficacy of yoga in balancing the deranged biochemical profile in healthy perimenopausal women hailing from South Kanara district of Karnataka, India. Asian J Biomed Pharm Sci. 2015; 5(45):20.
15. Prasad K Sunita, M, Raju, P, Reddy S, Sahay, B.K, Murthy, K. (2006). Impact of pranayama and yoga on lipid profile in normal healthy volunteers. Journal of Exercise Physiology Online. 9. 1-6.
16. Khatri D, Mathur KC, Gahlot S, Jain S, Agrawal RP. Effects of yoga and meditation on clinical and biochemical parameters of metabolic syndrome. Diabetes Res ClinPract. 2007 Dec; 78(3):e9-10.
17. Ranjani H, Jagannathan N, Rawal T, et al. The impact of yoga on stress, metabolic parameters, and cognition of Indian adolescents: Cluster randomized controlled trial. *Integr Med Res*. 2023;12(3):100979. doi:10.1016/j.imr.2023.100979
18. Shashikiran HC et al. Impact of naturopathy and yoga based intervention on atherosclerotic cardiovascular disease risk among metabolic syndrome individuals–A prospective single arm study. Brain Behav Immun Integr. 2023;4(n.d.):100020.
19. Sohl SJ, Birdee GS, Ridner SH, Wheeler A, Gilbert S, Tarantola D, et al. Intervention Protocol for Investigating Yoga Implemented During Chemotherapy. Int J Yoga Ther. 2016 Jan; 26(1):103–11.
20. Asiah ASS, Norhayati MN, Muhammad J, Muhamad R. Effect of yoga on anthropometry, quality of life, and lipid profile in patients with obesity and central obesity: A systematic review and meta-analysis. *Complement Ther Med*. 2023;76:102959. doi:10.1016/j.ctim.2023.102959
21. Yadav R, Yadav RK, Pandey RM, Kochar KP. Effect of a Short-Term Yoga-Based Lifestyle Intervention on Health-Related Quality of Life in Overweight and Obese Subjects. *J Altern Complement Med*. 2016;22(6):443-449. doi:10.1089/acm.2015.0268
22. Shetty, B., G. B. Shetty, M. Shantaram, and M. N. K. “Impact of Short Term Yoga on Anthropometric Measures, Body Composition and Serum Lipid Profile in Overweight

and Obese Adults: A Pilot Study". *International Journal of Research in Medical Sciences*, vol. 6, no. 10, Sept. 2018, pp. 3315-9, doi:10.18203/2320-6012.ijrms20184039.

23. Satyanand V, Reddy B, Lilly N, Shaik MV, Shaik A. Studying the role of yogic Pranayama in the management of Blood pressure. Int J Biomed Adv Res. 2014 Dec 25;5:609–11.
24. Sujatha T JA. Effectiveness of a 12-week yoga program onphysiopsychological parameters in patients with hypertension. Int J Pharm Clin Res. 2014;6(4):329–5.
25. Kalaiselvi G SK. Effectiveness of Yoga therapy on mild pregnancy induced hypertension. Asian J NursEduc Res. 2021;11(1):2024-04-11 00:00:00.
26. Singh A et al. Impact of yoga on blood glucose level among patients with type 2 diabetes mellitus: A multicentre controlled trial. J Stem Cells. 2018; 13(1):49–55.
27. Hegde S, Adhikari P, Shetty S, Manjrekar P, D"Souza V. Effect of community-based yoga intervention on oxidative stress and glycemic parameters in prediabetes: a randomized controlled trial. Complement Ther Med. 2013; 21(6):571–6.
28. Karuppasamy G. Effect of yoga therapy on selected bio-chemical variables among diabetic mellitus middle aged men Virudhunagar district. Int J Yoga PhysiotherPhys Educ. 2018; 3(2):152–4.
29. Shah D et al. A clinical study of Haritakyadiyoga in the management of hyper triglyceridemia. Int J Res Ayurveda Pharm IJRAP. 2015;6(2):241–4.
30. Azami M, HafeziAhmadi MR, YektaKooshali MH, Qavam S. Effect of Yoga on Lipid Profile and C-reactive Protein in Women. *Int J Prev Med*. 2019; 10:81. Published 2019 May 17. doi:10.4103/ijpvm.IJPVM_487_17
31. Moses RG, Wong VC, Lambert K, Morris GJ, San Gil F. Seasonal Changes in the Prevalence of Gestational Diabetes Mellitus. *Diabetes Care*. 2016;39(7):1218-1221. doi:10.2337/dc16-0451